DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
College Park, MD

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

APR 7 2006

Donald Lapre
President/CEO
Torica Productions, Inc.
14809 S 25TH Way.
Phoenix, AZ 85048

Dear Mr. Lapre:

This is in response to your email of August 16, 2005 to the Food and Drug Administration (FDA) in which you responded to our July 19, 2005 letter concerning statements you were making for your product **THE GREATEST VITAMIN IN THE WORLD** at the Internet addresses http://www.greatestvitaminintheworld.com and http://www.thegreatestvitaminintheworld.com.

In our previous letter to you, we identified claims you made about your product for its benefits for diseases such as diabetes, stroke, heart disease, insomnia, cancer, and arthritis. We advised you that these claims were not claims that your product affects the structure or function of the body but, instead, were claims that the product is intended for use as a drug within the meaning of 21 U.S.C. 321 (g)(1)(B) of the Act. In your email, you advised FDA that you had revised your web sites and asked us whether your revisions have adequately addressed FDA's concerns. We have carefully reviewed your revised web sites and believe that they continue to contain claims, including the apparent addition of consumer testimonials, that subject your product to regulation as a drug.

Examples of some of the objectionable claims observed on your web sites include:

Blood Sugar Diabetes

Gymnema sylvestra [an ingredient in the product] studies show an amazing effect on human blood sugar levels with adult onset [diabetes]."

"If you or someone you know has diabetes or at risk of getting diabetes, spread the word and make sure they understand the critical importance of protecting their body from this deadly disease."

Cancer

"[V]itamin C supplement use was associated with a significantly lower risk for gastric cancer. An interesting note is that both studies refer to the increased intake of vitamin C from fruits and

vegetables. The Greatest Vitamin in the World uses only the most absorbable form of Vitamin C from Acerola Cherries."

"Another greatly researched nutrient for helping prevent cancer is Garlic [an ingredient in the product]."

Probiotics

"[Probiotics, an ingredient in the product,] promote health by secreting ... antibiotic-like substances.... [T]hese substances... have a wide range of activity against salmonella, pseudomonas, E. Coli, and other harmful food-borne bacteria."

Your web site now also contains disease claims in the form of personal testimonials, including:

"I've been living with a disease called Crohn's Disease for 40 years. It's a very debilitating disease...The Greatest Vitamin in the World has laid all the pain and all of the disabilities of the disease and put them off into the corner!"

"I've lived in a house that had mold in it. I became very, very ill...Once I started on the vitamin just recently...the pain completely left my body!"

"Before I started taking the Greatest Vitamin in the World, I was really stiff in my legs, a lot of pain in my back which all all came from my total knee implants and an injury in my back...When I started taking the Greatest Vitamin in the World within 5 days I noticed an improvement! I had 40-50% less pain...."

"I have been treated for clinical depression for the past several years and none of of the medications I was using seemed to work...I was introduced to the Greatest Vitamin In the World.... Now that I am taking this vitamin, I am feeling the best I have in years! I don't get sick anymore like I used to...."

In the January 6, 2000 Federal Register, FDA published a final rule on structure/function claims (65 Federal Register 1000). The final rule defined the term "disease" and provided ten criteria for determining when a statement about a dietary supplement is a disease claim. This document is available on the Internet at http://vm.cfsan.fda.gov/~lrd/fr000106.html (See 21 CFR § 101.93(g)).

The revised claims on your web site, including references to selected publications and consumer testimonials, continue to evidence that your product is intended to treat, cure, prevent, or mitigate diseases such as diabetes, cancer, arthritis, and other diseases. Therefore, the revised claims on your website remain disease claims and are not structure/function claims under 21 U.S.C. 343 (r)(6) (section 403(r)(6) of the Federal Food Drug and Cosmetic Act (the Act)). Accordingly, these disease claims suggest that this product is intended for use as a drug within the definition

of 21 U.S.C. 321(g)(1)(B) and that it is subject to regulation under the drug provisions of the Act.

Your products are not generally recognized as safe and effective for the above referenced conditions; therefore, the products are also "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

This letter is not intended to be an all-inclusive review of your web sites and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

If you need additional information or have questions concerning any products distributed through your web sites, please contact FDA. You may respond in writing to Kenneth M. P. Taylor, Ph.D., Chemist, Food and Drug Administration, Division of Dietary Supplement Programs, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you have any questions concerning this letter, please contact Dr. Taylor at (301) 436-1439.

Sincerely,

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Los Angeles District Office, Office Compliance, HRR-PA-240